K060489

JUL 2 1 2006

510(k) Summary
Dade® PFA-100® Platelet Function Analyzer
Dade® PFA-100® Reagents

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714
Attn: Radames Riesgo
Tel: 305.480.7558

Preparation date: July 11, 2006

2. **Device Name/ Classification:**
Dade® PFA-100® Platelet Function Analyzer and Dade® PFA-100® Reagents / Automated platelet aggregation systems, Class II
(21 CFR § 864.5700)

3. **Identification of the Legally Marketed Device:**

Dade® PFA-100® Platelet Function Analyzer (K970505 and K002885)

4. **Device Description:**
The PFA-100® system provides a tool for clinicians to use in the detection of platelet dysfunction induced by intrinsic platelet defects, von Willebrand factor (vWF) functional deficiencies, or exposure to platelet inhibiting agents. The PFA-100® system simulates, under high shear stress, the interaction of platelets with an injured blood vessel. These conditions allow the PFA-100® system to measure *in vitro* platelet function as related to primary hemostasis.

5. **Device Intended Use:**
The Dade® PFA-100® Platelet Function Analyzer and associated reagents are *in vitro* diagnostic devices intended to aid in the detection of platelet dysfunction in citrated human whole blood.

6. **Medical device to which equivalence is claimed and comparison information:**

The modified Dade® PFA-100® system is substantially equivalent in intended use and performance to the currently marketed Dade® PFA-100® system.

7. **Device Performance Characteristics:**
Different studies conducted by independent organizations have shown results that suggest good performance of the system when testing pediatric populations and good assessment of DDAVP treatment.

A summary of the different studies used in support of this submission is included in this section.

Summary of New Literature Demonstrating PFA-100 System Performance in Pediatric Populations

Attachment	Reference	Assay Used	Diagnosis	Results	No. of patients in study
4	Cariappa et al.	▪ Bleeding history ▪ Bleeding time ▪ Aggregometry ▪ Platelet count ▪ PT ▪ aPTT ▪ VWF assays ▪ Repeat testing after drug discontinuation ▪ PFA-100	▪ Platelet defects ▪ VWD	PFA: ▪ Sensitivity o CEPI = 100% o CADP = 87% ▪ Specificity o CEPI = 97% o CADP = 80% ▪ Efficiency o CEPI = 98% o CADP = 83% ▪ Sensitivity o CEPI = 100% o CADP = 80% ▪ Efficiency o CEPI = 98% o CADP = 80%	52
5	Lippi et al.	▪ VWF:Ag ▪ PFA-100	▪ Normal platelet function	PFA CT for CEPI and CADP not different in pediatric patients and normal adults	52

Summary of Literature Demonstrating PFA-100 System Performance in Management of Bleeding Disorders

Attachment	Reference	Assay Used	Therapy	Diagnosis	Results	No. of patients in study
6	Fressinaud et al.	▪ Bleeding history ▪ Bleeding time ▪ Platelet count ▪ VWF:Ag ▪ VWF:RCo ▪ FVIII activity ▪ RIPA ▪ VWF multimers ▪ PFA-100	▪ DDAVP ▪ VWF concent.	Congenital VWD	PFA CT normalized in 23 Type I patients after DDAVP infusion	41 (23 VWD Type I)
7	Koscielny et al.	▪ Platelet count ▪ PT ▪ APTT ▪ PFA-100 ▪ Bleeding time ▪ VWF:Ag ▪ Aggregometry ▪ Flow cytometry	None	▪ VWD ▪ Aspirin-induced platelet defect ▪ Other platelet defects	PFA Col/EPI CTs were prolonged in 250 of 256 (97.7%) patients with impaired hemostasis	5649
8	Koscielny et al.	▪ Platelet count ▪ PT ▪ APTT ▪ PFA-100 ▪ Bleeding time ▪ VWF:Ag ▪ Aggregometry ▪ Flow cytometry	▪ DDAVP ▪ None	▪ VWD ▪ Aspirin-induced platelet defect ▪ Other platelet defects	▪ PFA CTs normalized in 229 patients after DDAVP ▪ Blood usage same in patients after DDAVP and those with normal hemostasis ▪ Blood usage 8X higher in patients with untreated abnormal hemostasis than in those with normal hemostasis	▪5649 (256 impaired hemostasis in prospective study) ▪5102 (317 impaired hemostasis in retrospective study)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 21 2006

Dade Behring, Inc
c/o Radames Riesgo
Regulatory Affairs & Compliance Manager
Bldg 500, Mail Box 514
P.O. Box 6101
Newark, DE 19714-6101

Re: k060489
Trade/Device Name: Dade® PFA-100® Platelet Function Analyzer
Dade® PFA-100® Reagents
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated Platelet Aggregation System
Regulatory Class: Class II
Product Code: JOZ
Dated: 23 February 2006
Received: 24 February 2006

Dear Mr. Riesgo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

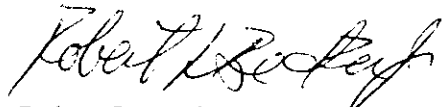
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060489

Device Name: Dade® PFA-100® Platelet Function Analyzer
Dade® PFA-100® Reagents

Indications for Use:

To aid in the detection of platelet dysfunction in citrated human whole blood.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060489